6. National Childhood Vaccine Injury Act Requirements (NCVIA)

The National Childhood Vaccine Injury Act (NCVIA) of 1986 was enacted to provide a cost-effective arbitration and compensation system for vaccine injury claims and reduce the potential liability of vaccine manufacturers. It also created a system for reporting and tracking adverse events related to vaccinations. Health care professional who administer vaccines must adhere to the following NCVIA requirements when administering vaccinations. Please note that these requirements apply to ALL vaccinations administered at your facility, not just those given through the VFC Program.

Vaccine Information Statements (VIS)

VISs are published by the CDC and provide information to vaccine recipients about the risks and benefits of each vaccine. **You must provide a current vaccine-specific VIS to your patient or your patient's legal guardian at each vaccination visit.**

VISs are updated periodically, and the CDC maintains the current print, audio, and foreign language versions on their website at http://www.cdc.gov/vaccines/pubs/vis/default.htm .

We recommend storing all VISs in one location and designating one person responsible for updating them. The CDC VIS webpage (link provided above) offers a "Get email updates" function whereby you are notified through email when VISs have been changed so you are prompted to update your stock.

Vaccine Adverse Event Reporting System (VAERS)

VAERS is a national vaccine safety surveillance program created through the NCVIA and co-sponsored by the CDC and the Food and Drug Administration (FDA). VAERS provides a nationwide mechanism through which adverse events following immunization can be reported, analyzed, and made available to the public. The VAERS website is http://vaers.hhs.gov/professionals/index.

Reportable Events – Required

The NCVIA requires health care providers to report:

- Any adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine
- Any adverse event listed in the VAERS Table of Reportable Events Following Vaccination that occurs within the specified time period after vaccination.

Reportable Events – Voluntary

You may report any adverse event that occurs after the administration of a vaccine licensed in the US. You may report adverse events even if you are unsure whether a vaccine caused them.

Vaccine Charting Requirements

The NCVIA requires that vaccination records be included in a patient's permanent medical record and that they include the following information:

- Name of the vaccine
- Date of vaccine administration
- Vaccine manufacturer and lot number
- Name and title of the person giving the vaccine
- Address of the clinic where vaccine was given
- Publication date of the VISs and date it was provided to the patient.

A number of resources are available for charting records. The Immunization Action Coalition website (http://www.immunize.org/handouts/document-vaccines.asp) provides free immunization charts (downloadable as PDFs) that capture all the information required by the NCVIA.